

# MUR70



**Take & Tell | 11 million reports | QPPV in Africa**

**Education to the fore | UMC on YouTube**



Marie Lindquist  
Director  
Uppsala Monitoring  
Centre

*A woman who has had a biopsy taken after mammography is called to a consultation a week later where she will be told what the result of the biopsy was. With the consultation appointment letter she finds a form requesting her to fill in “information required for surgery” – from which she draws the obvious conclusion that the result of the biopsy is that she has cancer and needs immediate surgery. She now suffers one week of agony before the appointment takes place, with no explanation and no available doctor to talk to.*

*Is this patient-centred care? No, it is not. It is one of many examples of modern health care turned into a mechanised delivery workflow where the demands of cost-efficiency (not unreasonable) have resulted in a system in which the patient is just an object (unacceptable!). Substantial medical advances have been made in recent years that have resulted in reduced morbidity and mortality. This is a great achievement, but, as any dedicated health professional knows, the ‘care’ in health care is not only about attending to peoples’ physical needs; a state of well-being cannot be attained without consideration of our emotional needs and responses, too.*

*Nowadays, pharmaceutical companies, regulators, pharmacovigilance centres, health clinics, hospitals, and, yes, UMC too – all of us produce slogans and taglines telling the world how patient focussed we are. I’m sure this is a reflection of a sincere intent – it certainly is in our case – but unless we demonstrate real empathy and respect for the individual in everything we do, can we genuinely say that we put patients’ needs first?*

*I’m going to repeat my mantra that the success of pharmacovigilance now and in the future relies on our ability to obtain and analyse the necessary clinical data in a way that interferes as little as possible with patient care; and to be able to show evidence that our work really helps patients, in the way that they want to be helped.*

*At two recent international meetings that I attended, the topic of accelerated market entry of innovative medicines was prominent (it wasn’t clear if the overall patient desire is for new drugs,*

*or effective treatments); I was glad to note that the corresponding need for better risk planning and safety monitoring is now also being discussed in this context. Of course we need effective new monitoring approaches, which will in a short time give us some idea of the effectiveness and risks of new products, particularly when large populations are exposed in countries with limited resources and ability to do regular post-marketing surveillance. I fully accept that in the near future safety monitoring in major public health programme rollouts of new medicines will be focussed and product based – so long as there is agreement that this is not the optimal long-term solution. Even now patients may take many medications in these countries – including herbal preparations – that also need monitoring.*

*Here I’m coming back to the patient, and my firm view that, in the long run, any clinical data collection must follow the patient, not the drug. A patient is not a disease – a patient is a person with one or more diseases, each requiring treatment, and with several drugs. A colleague of mine reported with horror that staff in one health clinic in an African country were requested to fill in up to seven different forms for each patient, repeating the same information, because they were treated with medicines through different public health programmes, focused on different drugs.*

*We need to convince hard-pressed health professionals that safety monitoring is worth doing. Every minute spent by a health professional filling in a form is a minute lost for patient care; if we don’t reduce the time and effort spent recording data, we will have difficulties. The failures of health care in my part of the world are repeated in most places – there is too little time for optimum clinical practice. Let’s not add to the problems unnecessarily.*

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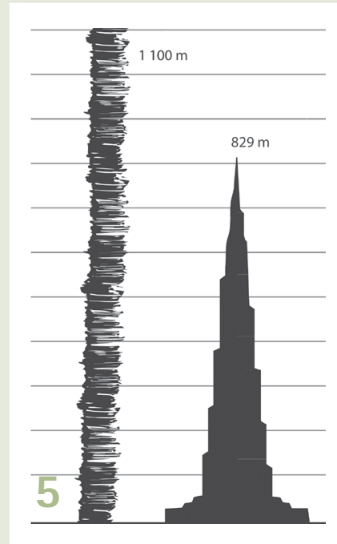
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- Building a global safety culture



Reports pile up

Finding trends in the increasing global database of ADR case reports.

VigiExperience

Students' view of the 2015 Uppsala course.



12-13



Take & Tell

A new initiative to boost patient reporting.

Many meetings

Pharmacovigilance is being discussed all over the world.



WHO Collaborating Centre for International Drug Monitoring

# Programme expansion

*Cecilia Biriell*

As we go to press news arrives from southern Africa and central Asia.

The national pharmacovigilance centre of the Kingdom of Swaziland has, through VigiFlow, submitted its first batch of adverse drug reaction case reports to VigiBase. The Ministry of Health of Swaziland applied for membership of the WHO Programme for International Drug Monitoring in September 2014. The Head of the national pharmacovigilance centre in Swaziland is:

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With working relationships established between the UMC and the national pharmacovigilance centre in Swaziland, the

country has been admitted as the 121<sup>st</sup> full member of the WHO Programme.

We are also happy to report that Tajikistan has applied to join the Programme. There is a pharmacovigilance group, formed in July 2014, and as an Associate member, they are now working to develop pharmacovigilance within the country with support from the UMC and experiences from other countries.

# Annual meeting website live

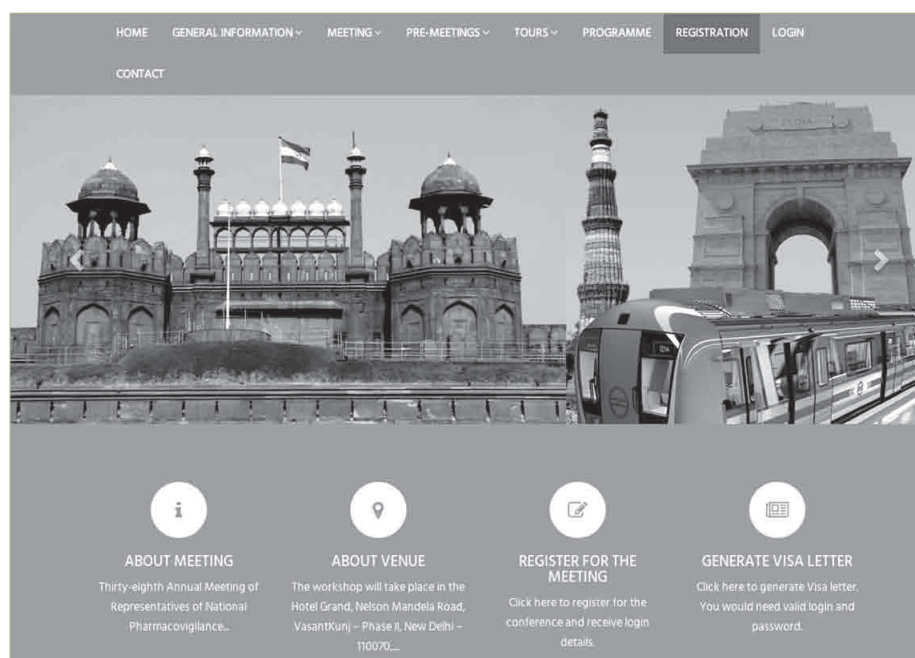
*Geoffrey Bowring*

A website for national centres intending to attend the 2015 meeting of the WHO Programme for International Drug Monitoring in New Delhi has now gone live at <http://whopvindia2015.com/default.aspx>.

The hosts, the Indian Pharmacopoeia Commission and the WHO Country Office, have made information about the meeting available, and representatives of WHO Programme members can now register their attendance and find out more at this website.

In addition to the main meeting (on 4-6 November) delegates can also take part in the usual pre-meeting on 3 November (entitled 'Let's talk PV!'), a workshop on 2-3 November on WHO ATC/DDD methodology and drug utilization research, and there are social activities being offered.

The 2015 Society of Pharmacovigilance India meeting is scheduled to take place in Kolkata from 31 October to 2 November.



# A birthday for Tunisia

*Magnus Ekelo*

Tunisia's National Centre celebrates 30 years of existence. The centre in Tunisia was one of the first of its kind in the Arabic world, and joined the WHO Programme in 1993.

The Minister of Health, Saïd Aidi paid an official visit to the Centre national de pharmacovigilance (CNPV) to mark its 30<sup>th</sup> anniversary. He praised the work of the centre in the field of monitoring of medicinal products and improvement in public health.

Directeur général of the CNPV, Dr. Mohamed Lakhel, responded and mentioned the need for an additional regional presence in the north of the country to complement centres in Sousse (central region) and Sfax (the south). Professor Lakhel also noted the logistical impact new responsibilities for liaison with the commercial sector will place on the CNPV, as well as the imminent creation of a bioequivalence unit.

We send our congratulations to our Tunisian colleagues on their birthday!

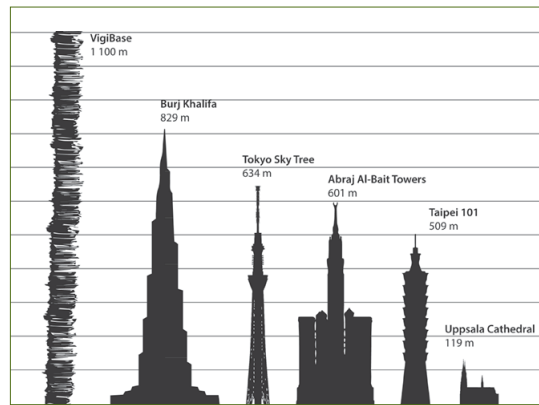


# VigiBase scales new heights

Anders Viklund, Cecilia Biriell

The number of individual case safety reports (ICSRs) in VigiBase is as always rapidly increasing. We reported a year ago (June 2014) that the total in the database had reached the milestone of 9 million ICSR; only a year later VigiBase contains over 11 million.

These case reports are easily accessible to all members of the WHO Programme for International Drug Monitoring through VigiLyze. If we had printed them on our usual office paper, the pile would reach 1,100 metres, 272 metres taller than the tallest building constructed by man, and the UMC offices would be crammed with paper. So we must all be grateful for modern IT techniques.



## Quantity

Generally, most of the two million increase from last year is caused by backlogs being sent from several countries. A backlog is an accumulated quantity of ICSRs submitted as a batch. This is a common reason for the quite big fluctuations in reporting rates from one year to another.

In this small study of reporting trends in VigiBase we have chosen to compare reporting during the last year (1 June 2014 to 31 May 2015) with the previous one-year period (see table below).

Some new countries have made it to the top 10 list of reporting countries during the last 12-month period. France and China have submitted backlogs, and therefore their percentage increase from the last period is close to infinity (see third column in table). The Netherlands is also new in the top 10 list for the last year, with a steady increase of consumer and Market Authorization Holder (MAH) ICSR.

Turning to reporting rate in relation to population size (in 2<sup>nd</sup> column of table), Korea and Singapore are in the top 10 countries during both periods, and we welcome France, Denmark and Croatia to the top 10. France is high up in the list due to the large backlog received during the year.

## Quality

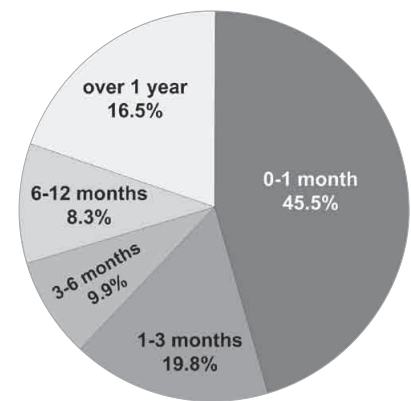
UMC has recently sent information about the completeness of the ICSR forwarded to VigiBase to all countries that have contributed at least 100 case reports during the last quarter. At UMC, an effort has been put into developing *vigiGrade* (the completeness score method), but we would like also to emphasize the equally important factors of reporting; quantity and timeliness.

These can be illustrated by a triangle:



The quality of reports, as measured by overall completeness score, has been calculated for the 42 countries that have reported a measurable number of case reports both during

the first quarter of 2014 and of 2015. The overall average score is very similar for the two years, 0.605 as compared to 0.613, which gives an increase that is hardly measurable. About one quarter of the countries have increased their score, while another quarter have a decreased score. For the rest of the countries there is very little change.



## Timeliness

The last factor in the triangle is Timeliness, which we usually illustrate by a pie-chart showing time since last submission of data. As we have shown above, several countries forwarded backlogs of data during the past year, which means that they are represented in the segments reporting during the last month up to three months, but if timeliness were measured from reporting from the primary reporter to the time when cases are available in VigiBase the time lag would be considerably longer.

The percentage of countries submitting case reports at least every three months has actually decreased from last year, from 77% to 65% of the 120 WHO Programme member countries.

Absolute numbers in period 2 (1 June 2014 – 31 May 2015)		ICSRs per million inhabitants in period 2 (1 June 2014 – 31 May 2015)		Highest increase*	
United States	920,573	Korea, Republic of	4,014	China	331,174%
new China	331,274	Singapore	3,810	France	235,771%
new France	235,871	new France	3,593	Russian Federation	1,373%
Korea, Republic of	200,704	United States	2,933	Zimbabwe	521%
Japan	46,379	Andorra	2,221	Mozambique	411%
Italy	44,201	Netherlands	1,218	Greece	237%
India	43,161	new Denmark	1,181	Colombia	231%
United Kingdom	30,104	Switzerland	1,047	United States	194%
Germany	26,416	new Croatia	768	Denmark	184%
new Netherlands	20,406	Italy	742	Brazil	146%

\* Period 1: (1 June 2013 – 31 May 2014) compared to Period 2: (1 June 2014 – 31 May 2015)

# Applying new data standards

*Helena Wilmar and Magnus Wallberg*

The end of April saw a group of UMC staff (Helena Wilmar, Magnus Wallberg, Jessica Nilsson and Jason Johansson) in London for two 'Information Days' on individual case safety report (ICSR) data management, organized by DIA (Develop. Innovate. Advance. – formerly known as Drug Information Association).



*Face to face in London*

## New format standard

Held at the European Medicines Agency (EMA) offices, 140 participants from a range of affected organizations gathered to discuss the new ISO/ICH ICSR data format standard and E2B (R3) package. The key changes this brings are in the application of the new ISO ICSR standard, which will impact EU adverse reaction reporting and electronic transmission activities such as EudraVigilance (EV). There will also be consequences for the UMC's VigiBase® and VigiFlow®.

## A range of changes

Some of the changes are in controlled vocabularies used in causality assessment,

the use of native language (EU languages), noting of tests and procedures, time interval for each event and the ability to record 'special situations' such as counterfeit, overdose, misuse and medication error. In addition, more detailed information can be recorded for each drug/event pair; another big change is that it will be possible to include attachments (like pdf documents or images). There were also discussions for stakeholders about implementation of the R3 changes.

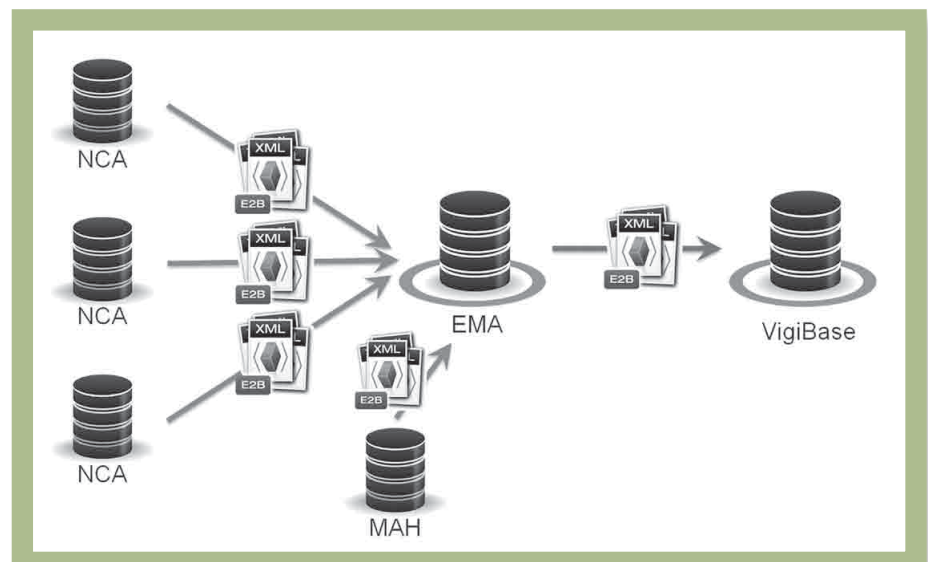
## Access and transfer

Implementation of the revised EV Access Policy will lead to increased access to adverse reaction reports for health

professionals and the public, weekly data provisions from within the European Economic Area (EEA) to the WHO database (at the UMC) and responsibilities for signal detection.

Magnus Wallberg presented current EMA/UMC collaboration on technical solutions for automatic weekly data transfer of ICSR batches to VigiBase, using an Application Programming Interface (API).

The shift from E2B R2 to R3 is actively ongoing within the EEA, Japan and the USA, although different national authorities are at different places along this route.



*Diagram from Magnus's presentation, showing the suggested future flow of ICSRs within EEA, from National Competent Authorities (NCA) via EMA to the WHO database (VigiBase).*

## GVP updates

EU Good Pharmacovigilance Practices (GVP) was updated at the end of April on the EMA's GVP webpage (follow links from [www.ema.europa.eu/](http://www.ema.europa.eu/) > Human regulatory > Pharmacovigilance > Good Pharmacovigilance Practices).

### Updates included:

- ◆ Clarification of EU reporting requirements for medicines donated outside the EU
- ◆ The draft of GVP Module XVI Addendum I was published for consultation
- ◆ An Introductory Note updated with the Module XVI Addendum I.

We hope to bring a full report, including other work in preparation, later in the year.

## Indicators manual

*WHO pharmacovigilance indicators – A practical manual for the assessment of pharmacovigilance systems*

Although there has been major growth in pharmacovigilance over the last 50 years, little attention has been paid to the development of indices which will provide a baseline and allow for assessment or quantification of the growth and performance of pharmacovigilance.

WHO has recognized this need by preparing a new booklet to provide a practical method for determining pharmacovigilance indices. It is designed to be simple, and can be understood by anyone in pharmacovigilance without formal training in monitoring and evaluation.

It should provide a useful tool for pharmacovigilance establishments. The current manual is being published as version 1.0, to underline its evolving nature: feedback from users will be welcomed. We hope to report further on the manual and its progress.

# Open access to global knowledge – take a look [www.vigiaccess.org](http://www.vigiaccess.org)

*Paula Alvarado*

Have you visited VigiAccess™ yet? Launched in April in Geneva, VigiAccess is a window to browse VigiBase®, the WHO database of suspected adverse drug reactions which holds more than 11 million cases, related to over 150,000 medicines and vaccines, from over 120 countries.

## Anyone can search

For the first time since its launch in 1968, VigiBase can now be searched by anyone in the world. UMC has developed an easy-to-use interface that can be accessed from a computer or smart-phone. Anyone with internet access can use the VigiAccess search engine to retrieve an 'at-a-glance' view of world-wide reporting of suspected adverse drug reactions for any medicine.

The launch of VigiAccess provides UMC with an opportunity to reach out to a wider audience and to kick-start Take&Tell (see centre spread, p12-13), a global pharmacovigilance awareness campaign, encouraging patients to be active about their health and well-being, and to talk to their doctors about any drug-related problem that is important to them.

## Pharmacovigilance for all

"To have a real impact on patient welfare and safety, pharmacovigilance must be an integral part of the healthcare delivery system – and also seen as a matter of critical importance for the whole of society", said Marie Lindquist, UMC Director, at the Geneva event.

Health care providers need to have access to the best possible knowledge based on the



*Dr Marie-Paule Kieny, WHO Assistant Director General for Health Systems and Innovation and Dr Marie Lindquist, UMC Director presenting VigiAccess at the launch in Geneva in April.*

latest evidence; and patients must be empowered to be an active partner in all aspects of therapeutic decisions affecting their own health. UMC hopes that by promoting open access and transparency, medicine awareness will increase.

## A pointer to risks

The data cannot be used in isolation to assess if a medicine is safe or unsafe to use – but it can serve as a pointer to potential risks that need to be assessed. Open access to data is an important feature of modern society, where people expect to be included in decisions regarding their health and well-being.

"What we are doing now is just a very small part of a very big and complex puzzle – but VigiAccess is a

significant symbolic step" Marie Lindquist added.

## Part of the dialogue

We hope that VigiAccess and Take&Tell will revitalise the dialogue between all stakeholders about

- The importance of pharmacovigilance
- The need to gather more, and better, data to feed into decision support systems
- The need to share data, competence and experience globally
- The importance of all of us (sooner or later we shall all be patients!) being engaged in the process.

We encourage you to visit VigiAccess and help us in building a truly global safety culture!

Do have a look!

*A full introduction to VigiAccess appeared on page 7 of Uppsala Reports 69 in April.*



*Dr Lembit Rago, Head, Regulation of Medicines and other Health Technologies talking to journalists and other guests at the launch.*



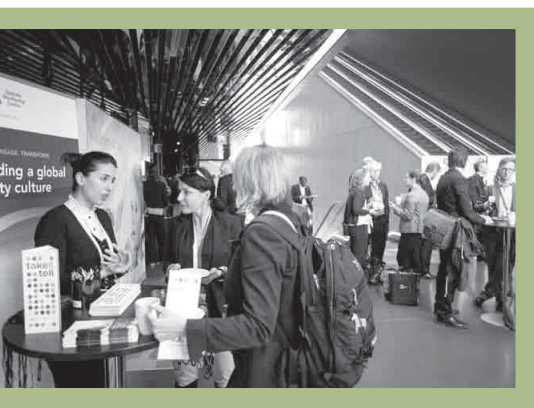
# Antimicrobial resistance – 21<sup>st</sup> century plague

*Antonio Mastroianni*

WHO's 2014 report on the global surveillance of antimicrobial resistance (AMR) revealed that antibiotic resistance is no longer a prediction for the future; it is happening right now, across the world, and is putting at risk the ability to treat common infections, in the community and in hospitals.



*Stefan Peterson at the 'Access not excess' workshop, which explored increased access to effective antibiotics while reducing excess use in low- and middle-income countries.*



*UMC's Berivan Semyan explains the Take&Tell campaign during one of the breaks.*

Without urgent coordinated action, the world is heading towards a post-antibiotic era, in which common infections and minor injuries, which have been treatable for decades, can once again kill.

## A partnership event

Uppsala Monitoring Centre was a sponsor of the two-day Uppsala Health Summit in June, which is an annual event that brings together different perspectives in a dialogue to address health challenges through better use of medical advancements.

The Summit is partnered and sponsored by representatives from industry, university and healthcare with long experience of healthcare development. The 2015 Summit focused on AMR and how to put the WHO global action plan into operation to reduce the threat of 'A World Without Antibiotics'.

"Antimicrobial resistance is a huge global problem. If we do not have effective treatment for infections, millions of lives will be at risk in every country", Marie Lindquist, UMC Director, asserts.

## Current threats

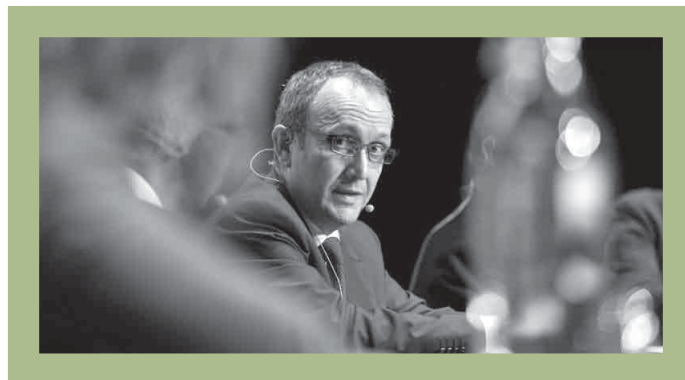
The first day set the stage with the current issues – irrational use of antibiotics by health professionals, farmers, veterinarians, commercial agriculture, and the impact this activity has on patient outcomes, agriculture, and the environment. The second day explored possible solutions and drafted recommendations.

## Message not getting through

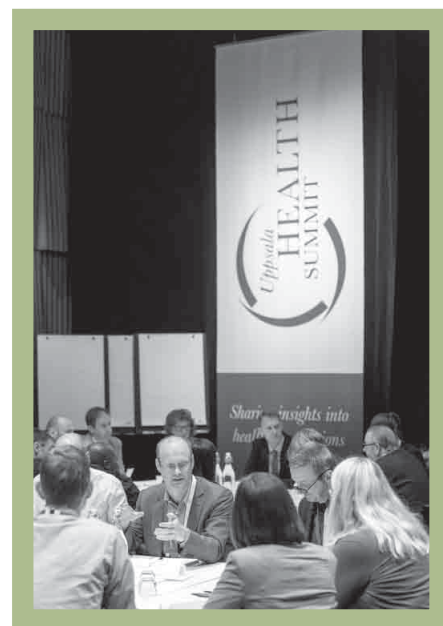
Despite channels of communication to doctors, veterinarians, farmers, and patients, the message is not effective, as the entire cycle is not being explained holistically and clearly. Whether antibiotics are irrationally used for patients or for animals, this has a negative impact on the longevity and efficacy of these medicines. Therefore, it is important for the public to understand how antibiotics are being misused and actively advocate for rational use to preserve human health, animal health, food safety, and environmental safety.

## Signals of resistance

"Global action needs to be communicated through educational campaigns about how we use antibiotics wisely" Lindquist adds. "We also need to improve ways to detect signals of emerging antimicrobial resistance so that we can prevent it from spreading."



*Gilles Forte presented the WHO Global Action Plan.*



*Discussions in full swing.*

## A public health necessity

Another key message to emerge from the dialogue was the need to redefine antibiotics as a necessity for public health, with less stress on the cost of production of antibiotics. Due to short treatment cycles there is not a viable business model to encourage pharmaceutical companies to innovate in antibiotics. Many companies instead invest in other types of medicines, diagnostics, and treatments. The result of this apathy is that society is on the cusp of having basic infections becoming untreatable and deadly. In response, many speakers advocated other structures to promote antibiotics, such as a sustainable global research and development fund, supported by major funding organizations and countries, to focus on AMR, emerging infections, and neglected diseases.

Dr Gilles Forte, Coordinator, Department of Essential Medicines at WHO, introduced the WHO Global Action Plan. This stimulated a major discussion, and the Uppsala Health Summit was seen as a key venue to move this forward.

*Credit, all photos - Mikael Wallerstedt*



# The 2015 VigiExperience

*Fidelie Kalambayi, Guillermo Lopez Rozada*

For two weeks from the 18<sup>th</sup> to 29<sup>th</sup> of May, the city of Uppsala was our home. We were 30 professionals from almost as many countries, attending the 17<sup>th</sup> Uppsala Monitoring Centre pharmacovigilance course. As in previous years, this renowned training gathered, for a VigiExperience™, participants from established or emerging national pharmacovigilance centres, from the pharma industry or the non-governmental sector. But what is the VigiExperience?

pharmacoepidemiology, pharmacoconomics, communication in general and risk communication in particular!

*It is good to have a different perspective, beyond that of the pharma industry (Gustavo Borghesi, Bayer Health Care, Germany)*



*Discussions round the table.*

and the day can sometimes be as long as you want it to be you might feel a bit pressured at first. But after a few days, you become fond of the Swedish punctuality and hence, efficiency.

After the day is done and you find yourself satisfied with what you learned, you will still have plenty of free time. You can go swimming or running, have dinner, visit Uppsala and Stockholm, go bowling or to karaoke and even go dancing. Not alone, of course. Did we forget to tell you? One of the most important outcomes of this training is that many of the participants will become your good friends, as it was this year for us, the self-proclaimed group of the VigiFriends. We still keep in touch, discussing pharmacovigilance, sharing jokes and memories, strengthening our relations.



*A question from the floor.*

*I found signal detection to be one of the most interesting topics during the course (Christine Cheung, Department of Health, Hong Kong)*

During intensive and very interactive days, we listened to great talks, engaged in fascinating discussions and had fun working in groups solving puzzles. Sherlock Holmes and Dr. Watson would have been proud of us!

*We are working to develop a post-market protocol for vaccines signals. We know the basics, but there is always a knowledge gap that one needs to fill out. (Nooshin Ahmadipour, Public Health Agency, Canada)*

Interdisciplinary work, cooperation and global interconnectedness were focal points in the course, since communities today need to acknowledge that building strong and cost-effective systems requires all the help they can get, from as many stakeholders they can involve.

*Teachers emphasised participants' interaction. They were very well prepared, I feel I learned a lot from them (Martine Ménard, Ministry of Public Health and Population, Haiti)*



*Bert Leufkens, a popular speaker.*

You are the kind of person who enjoys impressive public speaking? You will find for sure at least one UMC trainer who has them! You are more of a hands-on learning type? Yes! This training is the right place to be. The trainers will have dozens of exercises for you. And most of all, the trainers are well prepared and right on time. "Boring" is not a word that crosses your mind while you attend the UMC training sessions.

*Communication was one of the most interesting topics (Nana Ansah-Adjei, Food and Drugs Authority, Ghana)*

Yes, right on time. Because being on time is a very Swedish thing. If you come from a culture where time is not necessarily money

## Unexpected links

We arrived with an expectation to acquire more skills and deepen our existing knowledge, such as spontaneous adverse reactions reporting, signal detection, causality assessment, data management and analysis tools. But few of us knew that once you step back outside the field of pharmacovigilance, you can find related disciplines and fields that could help build a stronger pharmacovigilance. We had a great and pleasant surprise in sessions revealing the links between pharmacovigilance and

Should you attend the next pharmacovigilance course organized by the UMC? A definite "YES!" from us. Uppsala is a nice city, the UMC staff are really helpful and you will attend quality training sessions. And if not for these reasons, at least go and find your own VigiFriends in 2016!

*Fidelie Kalambayi, Romanian Angel Appeal Foundation, Romania*

*Guillermo Lopez Rozada, I+Solutions, Spain*

# Sharing the patient reporting experience

Linda Härmark

An early 15<sup>th</sup> century nunnery in Leiden – home of the Dutch National Museum for the History of Science and Medicine, named after the Dutch physician Herman Boerhaave – was the venue for a major international conference on patient reporting in pharmacovigilance. The Netherlands Pharmacovigilance Centre Lareb (WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting) organized the first Lareb conference on patient reporting on 23-24 April, with 60 participants from 21 countries.

## Signals

A series of lectures underlined the role of patient reports in signal detection. Practical instances were presented of experiences in Sweden relating to patients using anti-depressant drugs. From the Netherlands came examples of signals where patient reports had played a major role in identifying, for example SSRIs and persistent loss of sexual drive, SSRIs and aggression and vitamin B6 and neuropathy. An overview was given of the contribution of patient reports to signal detection in the UK. The day culminated

several European countries as well as research into the development of an instrument for patients to assess their symptoms as potential ADRs, and an investigation of the experiences of people who had recently suffered an ADR.

## Public awareness

The last session was an exploration of how to raise awareness for patient reporting, with examples from the Netherlands and Croatia. The last speaker was Nabarun Dasgupta from Epidemico whose inspiring talk demonstrated how information given by patients through social media can be used for pharmacovigilance purposes.

If you are interested in the field of patient reporting, all presentations from the conference are available on <http://www.lareb.nl/whocc/Conference-on-Patient-Reporting>

1. Banerjee A.K. et al. Patient-Reported Outcome Measures in Safety Event Reporting: PROSPER Consortium Guidance. *Drug Safety* (2013)36:1129-1149.
2. Leone R. et al. Effect of pharmacist involvement on patient reporting of adverse drug reactions: first Italian study. *Drug Safety* (2013)36:267-76.



Participants in the first Lareb conference on patient reporting

## Where have we come from?

The evolution of the role of patients in pharmacovigilance through the years was plotted by June Raine, of the Medicines and Health Products Regulatory Agency in London (and chair of the EMA Pharmacovigilance Assessment Committee). She also talked about how pharmacovigilance has to engage pro-actively with patients, and the challenges that we face when trying to optimize patient involvement in pharmacovigilance.

Bert Leufkens, professor of pharmaco-epidemiology at Utrecht University and Chairman of the Dutch Medicines Evaluation Board talked about the shifting focus from drugs to patients from a regulatory point of view. Ralph Edwards closed the first session with a talk about the value of Patient-Reported Outcome measures in Safety Event Reporting and the work that has been undertaken by the PROSPER consortium.<sup>1</sup>

in a lively panel discussion with the plenary speakers; it was agreed by all that patient reports are an important source of information in pharmacovigilance and that more development in this area is needed to make full use of the information patients provide.

The second day began with presentations on how to set up and run patient reporting systems, and practical experiences from the Netherlands and Italy were shared. A very successful approach has been introduced in Italy involving community pharmacists to promote patient reporting.<sup>2</sup>

## Workshops and free papers

Participants had a choice of three workshop sessions to get involved in, and they had also been invited to submit abstracts to the conference, which resulted in a diverse selection of short papers. These encompassed initiatives involving patient reporting in



# Retreat in Seoul

*Sten Olsson*

The Strategic Priority Group (SPG) of the WHO Global Vaccine Safety Initiative (GVS) met for a mid-year retreat on 9–10 May 2015. The seven SPG members assemble for these regular meetings to discuss and interact with staff from Safety & Vigilance at WHO headquarters and regional vaccine safety officers. In all, approximately 20 individuals got together. This time the meeting was held at the International Vaccine Institute (IVI) in Seoul, Republic of Korea, to allow coordination with the annual IVI vaccinology course (see below) and was welcomed by Laura Digilio, Head of Development and Delivery at IVI.

## New member

The SPG chairman, Alex Doodoo, started by wishing a new member, Adiola Seldaña Vidal, a warm welcome to the group. Adiola is head of vaccine pharmacovigilance at the regulatory authority in Chile.

## Strategic plans

Among the important tasks for the group to consider was the GVS Annual Report 2013–2014, a suggested framework for monitoring

and evaluation of completed projects and proposed new projects for inclusion in the project portfolio. The group also discussed how to refine its strategic instruments beyond the project portfolio which was considered to be most useful for activity follow-up. The strategic challenges facing the GVS in view of the expected imminent introductions of important new vaccines in resource-limited countries were also discussed.

## Global reports

In addition to the strategic planning, the agenda of the meeting covered sessions on recent developments. Robb Butler from WHO-EURO reported on the vaccine safety communication guidelines and training programmes developed, and offered them for adaptation and use globally. Sten Olsson from UMC explained a new approach for vaccine safety signal analysis developed by the UMC research and signal analysis team. It uses the vigiRank statistical analysis tool combined with an agile signal review approach (see UR69) and has proved to be more successful than previous working



*Robb Butler, WHO Europe, Isabelle Sahinovic, WHO Geneva and Madhava Balakrishnan, WHO Geneva, in Seoul.*

models. Ajit Pal Singh and Deok Ryun Kim, IVI, demonstrated the VAEIMS data management tool for AEFI reports.

The group also discussed the agenda for the next GVS stakeholders meeting, planned to be held on 14–15 October 2015.

# Safety at IVI course

*Sten Olsson*

The International Vaccine Institute in Seoul, Republic of Korea (IVI, [www.ivi.int](http://www.ivi.int)) is a non-profit international organization, established in 1997 by the United Nations Development Programme with the mission to discover, develop and deliver safe, effective and affordable vaccines for developing nations.

## International group

This year IVI offered its 15<sup>th</sup> international advanced vaccinology course on 11–15 May. It had attracted more than 90 participants and 30 eminent speakers from many parts of the world. The programme covered a wide spectrum of subjects (see box).

## Safety sessions

Half a day of the clinical development section was devoted to safety and vaccine pharmacovigilance. Speakers in this session



*Venue for the IVI course.*

- Epidemiology
- Immunobiology
- Vaccine discovery and process development
- Vaccine clinical development for licensure
- Vaccine introduction to use
- Vaccine use and acceptance

came from the WHO HQ, UMC, PATH, (Program for Appropriate Technology in Health) and the Center for Disease Control, USA. Madhava Balakrishnan from WHO gave an introduction to vaccine pharmacovigilance and Sten Olsson gave the UMC presentation 'Looking out for the unexpected – Cohort Event Monitoring and Signal Analysis'.



# A soul song for patient safety

Paula Alvarado

Active reporting of harmful side effects from medicines would significantly improve the welfare of patients and decrease public health spending – so says the song (kind of)

Through a new campaign with a song and a website – Take&Tell – Uppsala Monitoring Centre (UMC), is urging everyone to take a more active role in the management of their own health and in pharmacovigilance.

Quick reporting of the harmful effects of medicines to doctors and then national authorities would greatly improve global and national health. By reporting the side effects they experience to their doctors, nurses or pharmacists, citizens can help make drugs safer for everybody and contribute to reducing public health costs.

"Pharmacovigilance is about science and methodology, but it is fundamentally about people." said Marie Lindquist, UMC Director. "Medicines contribute enormously to our well-being, but they do not come without risk in the

form of side effects and adverse reactions. All of us, not only patients, will benefit from more knowledge and understanding of what the risks are and what we can do to reduce them," Lindquist added.

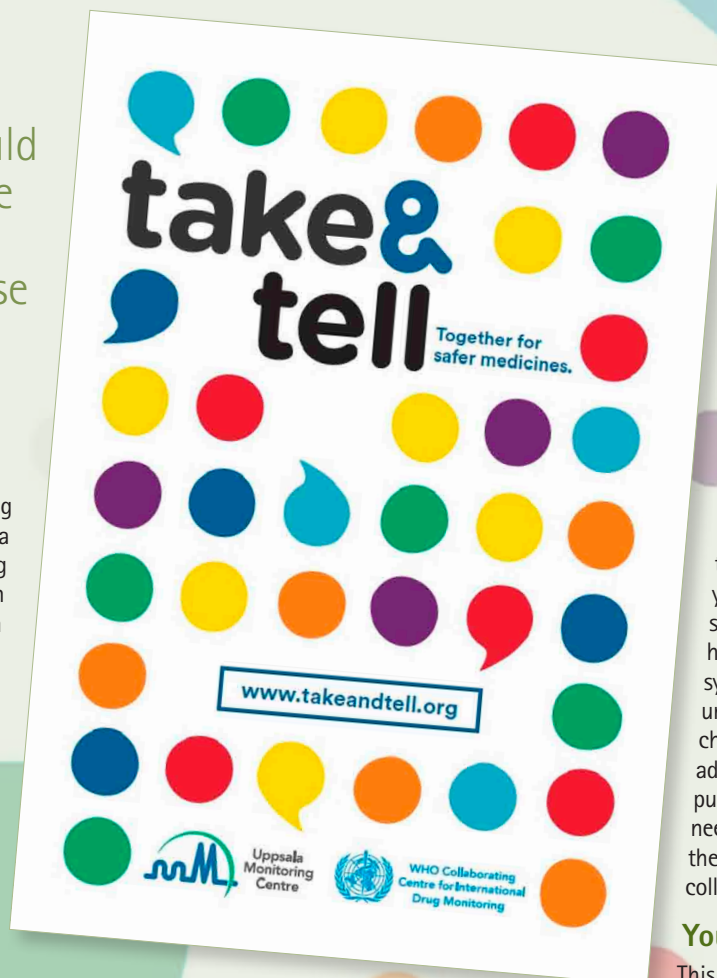
## A role for everyone

Better drug safety can be achieved through more active collaboration and information sharing between patients and doctors and the collection of good safety data nationally. Without reported information on unwanted side effects action cannot be taken to improve treatment and drug development. Everyone has a role to play in pharmacovigilance, in making drugs as safe as possible.

Adverse reactions are hugely underreported – estimates suggest about 95% go unreported; they account for thousands of injuries and deaths every year across the world; they represent a significant percentage of the causes of hospital admissions; safety reporting systems in many parts of the world are underfunded and hardly up to the challenge; the costs associated with adverse reactions are a huge burden on public health budgets. It is clear that we need to know more about them; manage their risks more effectively; invest and collaborate actively to reduce their impact.

## You're an expert

This is part of a greater shift in medical thinking: people themselves are the experts when it comes to their own health, and their experience needs to be shared for the good of all. This knowledge needs to be tapped and put to use, and UMC is supporting this movement through its latest campaign.



## Take&Tell - A global campaign - with a soul - to encourage people to report side effects of medicines.

The aim of the Take&Tell campaign is to raise global awareness of the importance of pharmacovigilance and to change the way people view the process of taking medicines. First and foremost the campaign aims to facilitate dialogue between doctor and patient about any medicine-related problem.

### The importance of frank dialogue

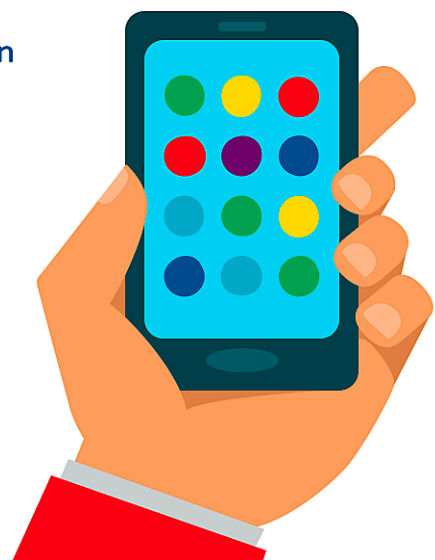
"Patients often discontinue a treatment because of side effects without talking to their healthcare professional; side effects that are shared with doctors are not always reported and so do not increase collective knowledge; medicine-related harm is not always recognised as such," said Pia Caduff, Chief Medical Officer at UMC. "A frank dialogue between patients and doctors is of the utmost importance to ensure effective and safe treatments, and for new information to be recognised and passed on," Caduff added.

### A song and an app

The campaign seeks to support people in being more active agents in their own health and, through consequential improvements in the safe use of medicines, contribute to better well-being for all. The core of the campaign are the catchy Take&Tell soul song that comes with a label warning - you can't get it out of your head - and its app that allows everyone to

## Download the Take & Tell application

Take & Tell application helps you keep track of any possible side effects to medicines. It's also a good tool for sharing the information with your doctor.



track their side effects and report them to their doctor. The site also offers downloadable educational materials in English, French and Spanish.

### Get in touch

Do you want to know more about this campaign? Contact Paula Alvarado, Head of Global Communications [paula.alvarado@who-umc.org](mailto:paula.alvarado@who-umc.org)

Visit our website: [www.who-umc.org](http://www.who-umc.org) and the campaign site: [www.takeandtell.org](http://www.takeandtell.org)

"Through the Take&Tell campaign song - the first song ever in pharmacovigilance - we wanted to make the message as simple as possible and bring it closer to home - pharmacovigilance might be a difficult word, but its message concerns everyone," Paula Alvarado, Head of Global Communications at UMC, concluded.





# Ghana leads in Qualified Person training

*Hudu Mogtari and Delese Mimi Darko*

The Ghana Food and Drugs Authority (FDA) launched a major initiative in May 2015. Statutory provisions empower the FDA to take any steps to protect the public in so far as food, medicines and household chemicals are concerned.

The Public Health Act, 2012, and Ghana FDA 'Guidelines for Selection of Qualified Persons for Pharmacovigilance (QPPV)', make it mandatory for marketing authorization holders and local representatives of pharmaceutical manufacturers to employ a qualified person responsible for pharmacovigilance, resident in Ghana, who oversees the safety monitoring of products marketed in the country. These requirements further state that the QPPV should receive formal training, recognized by the FDA.

As there are very few training providers in Africa, the FDA has joined with the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, University of Ghana, to launch such a course.

## First comprehensive course

The FDA and WHO CC, with the support of a former EU QPPV who is resident in Ghana, developed a comprehensive training course for persons wishing to become a QPPV. This vital new course has a minimum of 60 hours contact time and was designed to meet the busy schedule of senior pharmaceutical company executives.

The first training course for would-be QPPVs started on 20 May 2015 and ran over three weeks, with lectures on three days each week. The nine modules included:

- Introduction to pharmacovigilance;
- The QPPV, Legal framework, roles and responsibilities;
- Pharmacovigilance quality system;
- Individual Case Safety Reports, Data management, Coding and case causality assessment;
- Pharmacovigilance methods;
- Periodic Safety Update Reports and Periodic Benefit Risk Evaluation Reports;
- Signals and signal management;
- Pharmacovigilance audits and inspections; and
- Communication and crises management in pharmacovigilance.

At the end of the 60 hours (which involve both theory and hands-on exercises) participants are expected to:

- be familiar with the roles and responsibilities of the QPPV
- have an understanding of all relevant aspects of pharmacovigilance required in order to take on the role of QPPV

- understand how to monitor the performance and effectiveness of the pharmacovigilance system and its quality system
- be able to set up and run an efficient pharmacovigilance system in Ghana and be able to compile regulatory documents (PSUR/PBRER and RMPs), as per the FDA's requirements.

Barring any hitches, the FDA has set a deadline of 30 June 2015 to commence implementation of the pharmacovigilance provisions in the Public Health Act, 2012 and this training is one step closer to the realization of this objective.

## Broad participation

Participants for this first phase of QPPV training included local executives of Astra-Zeneca, Bayer, Roche, Pfizer, MSD, Novartis, Novo Nordisk, Eli Lilly, Servier, Janssen, Sanofi, Merck and GlaxoSmithKline.

The second phase, scheduled for the third quarter of 2015, will be open to importers and local manufacturers of pharmaceutical products. Regulators and pharmaceutical company representatives from other African countries are invited to participate. Tailor-made courses will also be run for the 60 hours but for shorter or longer duration based on demand.

## Future hopes

It is hoped that the involvement of pharmaceutical companies in the safety monitoring of marketed products in Ghana will result in an improved reporting rate of adverse events, which stands at an average of 12 reports per million population per year, and enhance the chances of signal detection, leading to greater patient protection to improve public health and safety.

For further information contact the FDA via [drug.safety@fdaghana.gov](mailto:drug.safety@fdaghana.gov) or [info@who-pv africa.org](mailto:info@who-pv africa.org)



*Chief Executive of the Ghana FDA, speakers and participants in the Accra QPPV course.*



## New audiences in China

Zhurong Liu

The size and population of China mean that fresh audiences are still getting introduced to the pharmacovigilance fold. A May visit by UMC staff encountered more new faces, and new challenges.

### Journal gathering

A conference organized by the China ADR Journal in Beijing allowed Ralph Edwards to speak on signal detection and analysis to a large gathering of professionals from hospitals – pharmacists and doctors. Around 90% of ADRs are collected by hospital pharmacists in China, so relevant training for them is vital. Ralph's topic was pertinent because it is quite new for clinical doctors and pharmacists and opportunities to hear such presentations are rare.

### Device monitoring

After a visit to the Institute for Executive Development, Ralph spoke next at a conference organized by the National ADR Centre. This centred on adverse events (AE) induced by medical devices, a new component of monitoring at the centre. More medical devices are being used in

China, and in 2014 about 260,000 AEs were collected. The talk was much appreciated and the Centre took the opportunity to invite UMC staff to return in the future.



*Ms Yan Suying, of the Editorial Board of the China ADR Journal, and Mr Jiang Deichun, deputy director of pharmacy department, both from Xuanwu Hospital of Capital Medical University talking with Ralph Edwards in Beijing.*

### In the regions

Next port-of-call was Zhejiang Province on the east coast, where the regional CFDA welcomed us for discussions and presentations. Marie Lindquist focused on the importance of public connections and

communication, and described how data flows from initial ADR information through to helping professionals in industry and regulators, and the public, in safer use of medicines. She also stressed the importance of engaging with ADR reporters, and introduced VigiAccess.

### Huge amounts of data

Ralph talked about signal detection and analysis in VigiBase. The China National ADR Centre has received a huge amount of ADRs. Similarly, each provincial ADR centre also receives a lot of ADRs. Each centre, last year, received on average 70,000 case reports.

### Meeting customers

Final stop on the itinerary was the DIA conference in Shanghai. More and more companies are expressing interest in our China Drug Dictionary, which is encouraging. At short notice an expert introduction to ATC was put together for the newly-founded National Centre for Medical Data which is going to introduce the ATC system in their database.

## Meeting of minds in São Paulo

Elki Sollenbring

The International Society of Pharmacovigilance (ISoP), in collaboration with ANVISA (the Brazilian regulatory agency), Sindusfarma (representing the pharma industry in the state of São Paulo) and ISoP's Latin America chapter held a well-attended training course on 26-28 March in São Paulo.

Experts from Brazil and further afield led talks, discussions and practical exercises. The programme particularly addressed pharmacovigilance in the context of the Brazilian health system and specific issues for emerging countries. This was a rare chance for an enthusiastic audience to engage with speakers with broad knowledge on safety monitoring from across the region and beyond.

It was an excellent opportunity for like-minded professionals from different backgrounds in Latin America to meet, and emphasized the need and desire for pharmacovigilance training in the region.

There was a mixed delegation from the UMC (signal detection, country support and communication) presenting, and on hand to answer questions about aspects of the WHO Programme.



*ISoP in São Paulo*

# WEB-RADR charges into battle

*Magnus Wallberg*

Victor Hugo's "morne plaine!" was not so dismal for the participants in the WEB-RADR WP3 working group, who met, just over 200 years after a more confrontational gathering nearby, at the wonderful UCB\* site in Braine-l'Alleud, close to Waterloo, outside Brussels. Invited by Stéphanie Bodin-Pärssinen of UCB we'd gathered to dig into the details of the mobile ICSR reporting app which is one of the deliverables in the WEB-RADR project.

## Green idyll

The idyllic site was scattered over a large area with lots of green grass, trees, flowers and ponds as well as swans and rabbits. The meeting room was lovely with trees just outside of the big panorama windows and rabbits jumping around on the grass.

But we were there for work: Phil Tregunno (Medicines and Healthcare Products Regulatory Agency), Linda Härmark (Lareb), Darko Krnic (Agency for Medicinal Products and Medical Devices of Croatia), Magnus Wallberg (Uppsala Monitoring Centre) Sieta de Vries (University Medical Centre Groningen) and Lucas Baptista and Kyra McKenna (Epidemico), alongside our host Stéphanie .

## Added value app

We were looking at the details of the planned reporting app – such as what information to ask for, in what order and how to ask for it. More importantly though, was our determination to add extra value to the app, compared to paper-based and normal web-based reporting, leading to discussions around functions not very common as of today.



*Waterloo's green side: the WEB-RADR project team at work*

The functions we wanted to include before the app's launch in Croatia and the Netherlands? The inclusion of attachments, images, the opportunity to give follow-up information, and the possibility to use the 'dictate' functionality already available in most modern smart-phones. Clever ways of asking for complicated information, for instance dosing, were discussed at length.

We had very interesting, sometimes tough skirmishes over the two days, but we also had much fun together in the group, and the value of meeting face-to-face should never be underestimated.

## A meeting with destiny

The meeting days were long and we worked really hard but Linda and myself took the opportunity to take a morning run before

breakfast to the famous landmark at Waterloo, the Lion Hill, where Napoleon met his destiny (with a bad outcome – for him).

The outcome for WEB-RADR only time can tell, but the general impression and feeling of all was that we in the WEB-RADR project will be on the winning side!

For more:

<http://web-radr.eu/>  
<https://twitter.com/WEBRADR>  
 @WEBRADR  
 @cmwallberg

\* Union Chimique Belge

# Warm welcome in cold Ottawa

*Helena Wilmar*

At the end of January Helena Sköld and myself visited the offices of Health Canada in Ottawa to re-establish collaboration with the National Centre. Our discussions focussed mainly on VigiLyze, where Canada is one of the most active countries, and whose input will be valuable in charting its future development. We also looked at vigiMatch, the role of pilot countries in its development, and at concerns about ICSR transmission to the WHO database.

## Mandatory reporting

National centre Head Lucie Olson prepared an excellent meeting and gave us an

introduction to a newly-passed law that will make reporting ADRs mandatory for Canadian health care professionals. Health Canada staff also set out their thoughts on features and wishes for UMC tools.

The Acting Director of the agency, Vicky Hogan, expressed a wish in her closing remarks for further direct exchange between the UMC and Health Canada.



# PHPs boost pharmacovigilance in Bogor

*Noha lessa*

Increased access to medications through implementation of Public Health Programmes (PHPs) in low- and middle-income countries such as Indonesia, has highlighted the need for strengthening pharmacovigilance systems.

Indonesia became a full member of the WHO Programme for International Drug Monitoring in 1975. The national centre is a unit within Badan POM (BPOM), the National Agency of Drug and Food Control. In preparation for forthcoming demands for use of active pharmacovigilance methods, BPOM conducted a successful workshop in Bogor, Indonesia, on 28–30 April. This provided an overview of fundamental principles and an introduction to Cohort Event Monitoring (CEM, an active pharmacovigilance method developed by the WHO Department of Essential Medicines and Health products, EMP).<sup>1</sup>

## TB, HIV/AIDS and Malaria

Indonesia, a highly-populated country with nearly 250 million people, is divided into 34 provinces, spread over approximately 17,500 islands. Common and high-burden communicable diseases in Indonesia include tuberculosis, HIV, malaria, and neglected tropical diseases (NTDs) such as yaws and leprosy. PHPs in Indonesia aim to control these diseases, some of which have started to introduce fast-track access of novel medications. With over 300 products in the pipeline for NTDs, tuberculosis, HIV/AIDS and malaria, the national centre is faced with

major challenges to monitor the safety of these medications.

The workshop was organized in collaboration between the WHO Country Office in Indonesia and WHO Headquarters. It was supported through a grant from the Access and Delivery Partnership project funded by the Government of Japan, coordinated and led by United Nations Development Programme. Representatives from the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance in Accra, Ghana, from WHO Headquarters (Geneva) and a pharmacovigilance specialist from the National Agency for Food and Drug Administration and Control in Nigeria presented and facilitated the workshop activities.

The aim of the workshop was to gather different stakeholders, i.e. health care providers, academics, staff working in national PHPs, members of the national centre, regulators and members of the ministry of health, and to strengthen their existing pharmacovigilance capacity.

The workshop took place over three days, commencing with opening remarks from the Director of Distribution Control of Therapeutic Products, Drs Arustiyono; representatives of the WHO Regional Office, Dr Salma, and the Pharmaceutical Services department from the Ministry of Health; and

Dr Shanthi Pal from WHO Headquarters. Day 1 continued with presentations on core aspects of pharmacovigilance, concepts, data management and tools. During the question and answer session the need for stronger collaboration between hospitals, PHPs, academia and national pharmacovigilance centres was highlighted.

## Integrating methods

Day 2 focused on the PHP setting, participants learning the importance of integrating pharmacovigilance into PHPs, and re-emphasizing the need for collaboration. A more detailed account of different methods was presented, and their appropriate uses were explained. Experiences of CEM were shared and participants were split into groups for discussion and role-play. Following this was an overview of causality assessment, with interactive exercises.

The focus on the final day was communication and crises management. Participants learned to assess risk, take actions to reduce risks and anticipate a plan for events that cannot be prevented. Examples of crises management cases and lessons learnt were shared. The last session consisted of group discussions on training and advocacy, resource management and communication.

1. Pal SN, Duncombe C, Falzon D, Olsson S. WHO strategy for collecting safety data in public health programmes: complementing spontaneous reporting systems. *Drug Safety*, 2013, 36(2):75–81.

# Sharing responsibility in Eritrea

*Mulugeta Russom, Elsa Mekonnen, Selamawit Ghebrehiwet*

The Ministry of Health of Eritrea, National Medicines and Food Administration, conducted its second annual National Pharmacovigilance conference from 17–18 April 2015 in Asmara, entitled 'Moving Eritrean Pharmacovigilance system forward: a shared responsibility'. The objective was to use this forum for pharmacovigilance partners to discuss problems of current interest and to bring them on board to play a major role in medicines safety monitoring and patient safety.

Original research papers, including a five-month national research on 'Burden of ADR among patients admitted to Eritrean hospitals', ADR case studies, risk management of some serious ADRs, situational analysis of antibiotic resistance and other relevant topics, were presented.

Iyassu Bahta, Director of the Eritrea FDA, in his opening remarks said "with the limited resource it has, the Eritrean Pharmacovigilance Centre is many steps forward and the current performance seems encouraging. With optimized partnerships, we can go further in safeguarding our public from being harmed unnecessarily with medicines related problems". He elaborated the roles and responsibilities of stakeholders as described in the National Pharmacovigilance Policy and advised that it is opportune for all partners to adhere to the policy in their shared responsibility for preventing adverse reactions and other drug-related problems.

Two colleagues from the UMC joined the conference, which was attended by over 140 people: public health programme managers, health professionals, senior Ministry of Health



*Participants at the Asmara conference*

officials, industry, UN partners, the WHO Country Office, academia and other partners.

Six healthcare professionals who had made important contributions in reporting ADRs in 2014 were given a 'Pharmacovigilante Award'. This award is among the key strategies introduced to maximize detection and reporting rate of ADRs in Eritrea.



# Netherlands national education programme

*Rike van Eekeren and Tim Schutte*

For medical, pharmaceutical and other health professional students, knowledge of adverse drug reactions is essential for rational and safe pharmacotherapy. Beyond this, future health professionals must be aware of their role and responsibilities to maintain and enhance the safety of medicines.

## Programme developed

The Netherlands Pharmacovigilance Centre Lareb is a WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting. Working with the Dutch Society for Clinical Pharmacology & Biopharmacy (NVKF&B) and the Research and Expertise Centre In Pharmacotherapy Education (RECIPE of VU medical centre Amsterdam), we have developed a programme for pharmacovigilance education. This programme can be used by all Dutch universities in their clinical pharmacology and pharmacotherapy curricula for medical students.

## Two elements

The programme encompasses problem-solving and a lecture. The problem-solving of adverse drug reaction cases is intended for undergraduate students. It focusses on the context and pharmacology of adverse drug reactions. Cases involving drug use during pregnancy and lactation are also part of the programme.

The second element of the programme is a 'do-it-yourself' lecture on the recognition and reporting of adverse drug reactions in daily practice, which can be used to teach students before or during their clerkships. The aim of this assignment is to let students report at least one adverse drug reaction to Lareb during their clerkships, in order to practice recognition of adverse drug reactions and to get familiar with the reporting procedure.

Although the national programme currently provides an opportunity for pharmacovigilance education for medical students, it has potential in other healthcare education curricula, such as those of specialist nurses and physician assistants.

We hope that this programme will prepare future health professionals who will know what, when and how to report adverse drug reactions and understand the importance of pharmacovigilance in everyday practice.

This educational programme has just begun in June 2015; we will report later on our experiences.

*Rike van Eekeren, The Netherlands Pharmacovigilance Centre Lareb*

*Tim Schutte, Research and Expertise Centre In Pharmacotherapy Education (RECIPE of VU medical centre Amsterdam)*

# Novelties on francophone course

*Loubna Alj*

This year's francophone training course – the 9<sup>th</sup> to be held in Rabat, Morocco took place in May. Twenty-nine participants represented an excellent range of African countries: Benin, Burkina Faso, Burundi, Chad, Congo Brazzaville, Equatorial Guinea, Ivory Coast, Mali, Senegal, Togo and Morocco. Three quarters of the group were pharmacists, with physicians and other healthcare professionals making up the rest.



*Francophone Africa in the Rabat sun*

New topics included a closer look at the 'Vigitools' (VigiLyze and VigiMine) as well as the pharmacovigilance of blood and blood products. The training also highlighted the major role of the pharmacist in their

drugstore in managing adverse drug reactions and preventing medication errors.

## Round-table with a journalist

Another novelty this year was having a 'round-table' on how to communicate during a crisis situation in pharmacovigilance. We invited a specialist journalist in the medical press and participants answered questions as in a live interview with three different crisis situations that pharmacovigilance centres could face in their work. Participants were also asked to write a press release on the three issues. The principles of good communication exposed by the journalist and advice on how to communicate in crisis were well explored.

## Rules for a pharmacovigilante

Finally, the course came up with '8 rules to be a good dedicated person in pharmacovigilance':

1. The pharmacovigilante does not await regulation, political will or optimal conditions to promote pharmacovigilance
2. The pharmacovigilante should be motivated and devoted to put in place pharmacovigilance in his country or workplace

3. The pharmacovigilante remembers to seek technical support from WHO and WHO Collaborating Centres
4. The pharmacovigilante looks for donors to finance its activity
5. The pharmacovigilante creates a network with Marketing Authorization Holders in order to build partnerships
6. The pharmacovigilante knows that awareness programmes are vital for promoting a pharmacovigilance culture
7. The pharmacovigilante encourages his colleagues and partners to participate in pharmacovigilance training courses and events and also visit experienced national pharmacovigilance centres
8. The pharmacovigilante pledges to put in place risk minimization actions to prevent adverse drug events.

Next year's event should be equally inspiring; the dates are already set for the 10<sup>th</sup> francophone pharmacovigilance training course from 9 to 20 May 2016.

# Africans learning pharmacovigilance – in Africa

Sten Olsson

Ten young healthcare professionals, five women and five men, from different parts of Africa, assembled with high expectations at 9am on 1 June 2015 in the offices of the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance (WHO CC) in Mango Tree Avenue. All had been admitted to the 5<sup>th</sup> Pharmacovigilance Fellowship course in Accra, Ghana. They would spend four weeks together while learning about all the intricate challenges involved in patient safety monitoring, and get to know each other in the process.

## Comparing experiences

They had come from Cape Verde, Gambia, Ghana, Malawi, Mozambique and Swaziland – which offered good opportunities for comparing experiences and getting new ideas. They were welcomed by the friendly course management team from WHO CC, telling them to be open and inquisitive and to let the course support team help them with all practical issues that might arise during their stay.



Fellowship of participants and teachers in Accra in June

The setting was ideal for creative discussions around the conditions for development of good pharmacovigilance practices in Africa. In addition to local expertise many resource persons from outside were brought in to contribute with different perspectives on the complex field of patient safety surveillance. Some lectures were given remotely via modern telecommunications and other contributions presented on site.

## UMC and WHO Programme

Representing the experiences of the UMC and the WHO Programme I had the privilege of sharing the first week of the course with

the group and could enjoy the interactive atmosphere and discussions. I appreciated the curiosity and eagerness to learn that I noticed from my younger colleagues. In return I could learn from them about real life in many different African settings.

In addition to theoretical lectures there were practical exercises, study visits and work on individual activity plans over the four weeks. It is important that Africans are being offered high-quality pharmacovigilance training in Africa.

## An important result

The presence at the course of Nomsa Shongwe, focal pharmacovigilance person in Swaziland, allowed us to sort out the outstanding technical obstacles for Swaziland's membership in the WHO Programme. A confirmation of Swaziland's status as the 121<sup>st</sup> full member country in the Programme arrived from Geneva while the course was still going on.

## Save the date for *Let's talk PV!*

3<sup>rd</sup> November 2015

Join a team of international experts during the UMC pre-meeting day preceding the 2015 WHO National Centres meeting in New Delhi, India. *Let's talk PV!* offers a day of interactive learning, dialogue and discussion on leading themes in pharmacovigilance.

- Latest scientific developments in the field of signal detection
- Impact communication: how do we tell the pharmacovigilance story?
- Pharmacovigilance in focus – how do we develop it in challenging scenarios?
- Sustainability of pharmacovigilance data management



*Let's talk PV!* faculty consists of speakers from national pharmacovigilance centres, regulators, academia and UMC. Take this opportunity to learn, share and network with pharmacovigilance colleagues and experts from all over the globe.

*Let's talk PV!* is open to all member countries of the WHO Programme for International Drug Monitoring.

## Back to Accra

The 2<sup>nd</sup> African Society of Pharmacovigilance (ASoP) conference is getting closer.

From 25<sup>th</sup> – 27<sup>th</sup> November 2015 the La-Palm Royal Beach Hotel in Accra, Ghana will be the meeting point. The theme: Pharmacovigilance in Africa: New Methods, New Opportunities, New Challenges.

Workshops on the 25<sup>th</sup> will be followed on the next two days by sessions focusing on new vaccines and medicines for tropical diseases, capacity development, methods for pharmacovigilance in Africa, clinical trials and much more.

Go to <http://asop2015.com/>



# Visitors from around the world....

## Morocco

*Anki Hagström*

UMC and the WHO Collaborating Centre Morocco (the Centre Anti Poison et de Pharmacovigilance du Maroc), have joint interests in the training and technical support for pharmacovigilance systems strengthening and patient safety.

Through a collaboration between UMC and the WHO CC Morocco, clinical pharmacologist Dr My Elhassan Elkarimi ('Hassan') from the Morocco centre was welcomed to Uppsala for a two-month secondment (13 April – 12 June).



*Hassan, from Rabat*

UMC Global Services section was responsible for hosting Hassan during his stay. He received training, an introduction and invitation to contribute to Global Services as well as other parts of the UMC. Hassan generously shared his knowledge and skills with us, and with course participants on the 17<sup>th</sup> Annual International Pharmacovigilance Training Course. In addition, Hassan's language skills enabled us to provide distance training in Arabic and French.

A secondment offers the ability to spend time together on a daily basis. It enables a closer sharing of experiences, an opportunity to learn from each other and builds stronger relationships. The aim of Hassan's stay was to enhance and to extend the collaboration between the UMC and the WHO CC Morocco, to the benefit of member countries in the WHO Programme for International Drug Monitoring.

## Namibia

*Cecilia Biriell*

Dr Assegid Mengistu of the Namibian Therapeutics Information and Pharmacovigilance Centre (TIPC) and Mr Evans Sagwa - the Country Director for the USAID-funded Systems for Improved Access to Pharmaceuticals and Services project (SIAPS) which is implemented by Management Sciences for Health (MSH) in Namibia - visited the UMC office on the 4<sup>th</sup> of June. The two were in town for the

Uppsala Health Summit 2015 'A World Without Antibiotics'.

As UMC responsible person for providing technical support to member countries of the WHO Programme in the African region, I had the chance to discuss the activities of the TIPC and the support that it requires from UMC in general. The UMC is currently supporting TIPC to implement eReporting and looked over recommended action points to overcome the current challenges. I underlined the need for closer collaboration between MSH and UMC in strengthening pharmacovigilance systems, especially in the emerging economies.

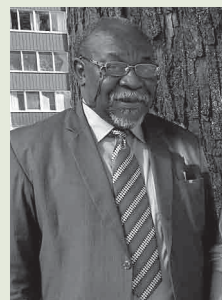


*Cecilia with Assegid and Evans*

Namibia has been a full member of the WHO Programme since 2008. The centre uses UMC tools such as VigiFlow and VigiLyze for managing its adverse reaction reports. By June 2015, Namibia had filed a total of 1,549 individual case reports in VigiBase, the majority (76.8%) related to antiretroviral-suspected adverse reactions.

## Nigeria

*Anki Hagström*



*Ambrose*

This spring, UMC once again welcomed Professor Ambrose Isah from Nigeria to Uppsala. He serves on the academic staff of the University of Benin Medical School, Nigeria, is Chairman of the National Drug Safety Advisory Committee, as well as the National Essential Medicines List/ Drug Formulary Committee, and is a member of the WHO Expert Panel.

Ambrose spent time in the Global Services section and generously shared his experiences from working with pharmacovigilance systems in low-resource settings locally and on a global level. His experience from public health programmes, essential medicines, managing pharmacovigilance activities in Nigeria and working with the WHO pharmacovigilance indicators has helped build competence in Global Services. This is of great value for us to deliver better capacity-building services to WHO Programme countries.

Ambrose also contributed as a speaker and expert in the 17<sup>th</sup> Annual International Pharmacovigilance Training Course. It is a privilege to be given the opportunity to tap into such an abundance of knowledge; he has left a lasting impression on our team and has become very dear to us. We hope to see him in Uppsala again soon.

## India

*Sten Olsson*

Gurumurthy Parthasarathi (Partha), Dean, JSS College of Pharmacy, Mysore, India, briefly visited the UMC in May this year, as he did last year. He gave a lecture at the UMC international pharmacovigilance course, and with the UMC training team evaluated the 1<sup>st</sup> Joint UMC-JSS pharmacovigilance training course in Mysore in February 2015 and planned for the next one taking place from 18–29 January 2016.



*Partha*

While developing closer working relationships with UMC he also met with representatives of the Faculty of Pharmacy of Uppsala University and researchers at the Department of Clinical Pharmacology, the Uppsala Academic Hospital, discussing future teaching and research collaboration.



## Research arrivals

Sara Hedfors has a Master of Science in Engineering Physics from Uppsala University. After graduation she worked at a small company in Enköping for five years, mainly with software and system development, but also with electronics, mechanics, customer relations and project management. Her strength is a broad spectrum of programming knowledge; she has experience in languages from assembler to C# (and lots of things in between).

Sara joined the UMC in May 2015, and will initially work mainly on a visualization project called ADR Spectrometry. "Pharmacovigilance is a new, but exciting, area for me and I look forward to experiencing my first signal sprint in September. I feel strongly motivated by the research focus, friendly people and do-good-spirit I have come across here."

During her spare time Sara's biggest passion for the moment is spending time in her (relatively new) big garden. She also enjoys reading books, playing the piano and exercise



(mainly running, biking and cross country skiing).

Jakob Rogstadius joined the UMC research section in 2015. His primary focus is on methodological research related to data

mining of pharmacological risks and benefits, from sources such as electronic patient records, public social media communication and search query logs. His research interests include data mining, natural language processing, data visualization, crowd-sourcing and situational awareness.

"Prior to joining the UMC, I pursued a PhD in Information Systems, in which I proposed new methods and tools for real-time monitoring of large-scale humanitarian disasters through semi-automated analysis of public communication in online social media. I have previous experience from building visualization and decision support systems for financial market surveillance, industrial asset surveillance, and analysis of socioeconomic indicators." A native Swede, he has lived and worked in Portugal, Finland, Qatar, Taiwan and Ethiopia.

In his spare time, Jakob enjoys exploring ideas and the world, including nature, travelling, TED\* talks, comic books and board games.

\* (Technology, Entertainment, Design)

## Diary dates

The UMC education team will be at home and away over the coming 12 months:

An **Inter-Regional Pharmacovigilance Training 2015** in Singapore takes place on 30 September to 2 October 2015. WHO, the Uppsala Monitoring Centre and the Health Sciences Authority of Singapore have been collaborating to conduct pharmacovigilance training for regulators from ASEAN and Asia Pacific countries since 2010.

Then in the New Year, it's back to Mysore, India for an **Asia Pacific pharmacovigilance**

**training course** in collaboration with JSS College of Pharmacy (18-29 January 2016) building on the success of this year's event.

The **18<sup>th</sup> International Pharmacovigilance Training Course** in Uppsala will be over two weeks on 16-27 May 2016, and this will be immediately followed by the UMC's 4<sup>th</sup> biannual Research Conference on 30-31 May 2016 - not to be missed.

More information on the 2016 events will be available via the UMC website.



## Drug Dictionary news

As of 1<sup>st</sup> of June 2015 the WHO Drug Dictionary Enhanced contains:

- 342,980 Unique Names
- 2,458,286 different medicinal products and trade names, including, for example, form and strength information.
- 13,395 different ingredients mentioned in these products
- Entries from over 133 countries.

To date, the UMC has conducted two international User Group Meetings, the first in early 2015 in Bangalore, India then in Washington DC in June that year. Additional User Group Meetings are planned in 2015 and we cordially invite you to join. This is the opportunity to interact with clients and colleagues in the pharmaceutical / CRO world and learn from other coders in the industry.

Dates for the 2015 are scheduled for:

- 16-17 September - Cincinnati, US
- 7-8 October - London, UK
- December (dates to be announced) - Tokyo, Japan

To register, your company needs to have an on-going WHO DD subscription. Go to the UMC User Group Portal, where you can access registration information and an agenda for each meeting.

## The Grand Finale of Monitoring Medicines

Sten Olsson

We have quite frequently reported on the activities and results of the Monitoring Medicines (MM) project, particularly during 2009 – 2013 when it was in its active phase. MM was a project conceived and written by Shanthi Pal at WHO, Geneva, coordinated by UMC, and with 11 partners in an international consortium which received a grant of approximately €2 million from the FP-7 framework of the European Commission. Its objectives were to:

- Support and strengthen consumer reporting of suspected adverse drug reactions
- Expand the role and scope of national pharmacovigilance centres to identify, analyse and prevent medication errors
- Promote better and broader use of existing pharmacovigilance data for patient safety
- Develop additional pharmacovigilance methods for complement spontaneous reporting systems.



After the project was successfully completed in 2013 the managers felt that it would be useful for the international community of pharmacovigilance scientists to publish the achievements of the project. One of the consortium partners, Dr Elliot Brown, had the idea of an issue of the journal *Drug Safety* dedicated to the activities and results of the MM project. The editor of *Drug Safety* together with the project managers Shanthi Pal and Sten Olsson, agreed to serve as guest editors for this special issue which was published in April 2015.

In addition to the introductory summary by the editors, describing the overall scope and results of the project, there are eight papers on specific results of the project itself or follow-on effects of MM. Three of the articles are open access publications freely available on the internet.

### Drug Safety

2015, Volume 38, Number 4 (pages 319 – 408)

1. S.N Pal, S. Olsson, E.G. Brown. The Monitoring Medicines Project: A Multinational Pharmacovigilance and Public Health Project. (open access)
2. K. Hartigan-Go. Empowering Consumers as Contributors for Health Product Safety: Lessons from the Philippines.
3. L. Härmark, F. Van Hunsel, B. Grundmark. ADR Reporting by the General Public: Lessons Learned from the Dutch and Swedish Systems.
4. D Cousins, D Gerrett, N. Richards, MM. Jadeja. Initiatives to Identify and Mitigate Medication Errors in England.
5. M. Plöen, M. Wallberg, S. Olsson. User-Driven Development of a Web-Based Tool for Patient Reporting of Drug-Related Harm.
6. S. Setkina, M. Dotsenko, S. Bondar, I. Charnysh, A. Kuchko, A. Kaznacheeva, E. Kozorez, A. Dodaleva, N. Rossa. Safety and Effectiveness of Highly Active Antiretroviral Therapy in Treatment-Naïve HIV Patients: Preliminary Findings of a Cohort Event Monitoring Study in Belarus.
7. K. Juhlin, G. Karimi, M. Andér, S. Camilli, M. Dheda, T.S Har, R. Isahak, S-J Lee, S. Vaughan, P. Caduff, G.N. Norén. Using VigiBase to Identify Substandard Medicines: Detection Capacity and Key Prerequisites. (open access)
8. R. Benkirane, R. Soulaymani-Bencheikh, A. Khattabi, G. Benabdallah, L. Alj, H. Sefiani, K. Hedna, L. Ouammi, S. Olsson, S.N. Pal. Assessment of a New Instrument for Detecting Preventable Adverse Drug Reactions.
9. H. Ndagije, V. Nambasa, E. Namagala, H. Nassali, D. Kajungu, G. Sematiko, S. Olsson, S.N.Pal. Targeted Spontaneous Reporting of Suspected Renal Toxicity in Patients Undergoing Highly Active Anti-Retroviral Therapy in Two Public Health Facilities in Uganda. (open access)

## Check out the You(MC)Tube

Anders Viklund

At UMC we have just said farewell to 30 highly motivated and determined course participants with different professional backgrounds from 28 countries. During two weeks they have been marinated in pharmacovigilance and are now ready to continue developing pharmacovigilance in their home countries.

Nothing compares to the real experience, but you still have the possibility to learn from this training – just watch some of the sessions on YouTube.

This year, seven course sessions were recorded by a professional film-maker. The sessions chosen complement and update the existing collection of UMC educational videos. With these new clips, UMC has around 50 recorded full-length lectures ranging across different topics.

- General pharmacovigilance
- Practical pharmacovigilance
- Communication
- Pharmacoepidemiology
- Risk Management

To share these lectures we have a YouTube channel – Uppsala Monitoring Centre. It is open to the public and no account or password is needed to access the channel. These could be of interest to anyone who would like to broaden their knowledge; they are not for complete beginners. Please see instructions below on how to find the channel.

### How to find the UMC YouTube channel:

Go to: [www.youtube.com](http://www.youtube.com)

Enter "Uppsala Monitoring Centre" in the top search field.

Click on the UMC logo

The UMC YouTube channel also contains other material; the Take & Tell song and instructional videos on our tools, so do visit Uppsala Monitoring Centre on YouTube.

## Bi-lingual Focus

Giampaolo Velo

The bulletin *Focus Farmacovigilanza* is now more than 20 years old. It's a member of the International Society of Drug Bulletins and is distributed in Italian as a pdf that can be downloaded for free from the website [www.farmacovigilanza.eu](http://www.farmacovigilanza.eu).

Now an English - and free - version, translating the Italian papers, is available online at [www.pharmaco-vigilance.eu](http://www.pharmaco-vigilance.eu), with the aim of reaching a more international audience. The bulletin is issued six times a year and is available only online, giving updates on all what is going on in the pharmacovigilance world.

The journal is made possible thanks to the funds and activity of the pharmacovigilance centres of the regions Veneto, Emilia-Romagna and Lombardia.

DATES	TITLE	PLACE	ORGANISER/CONTACT
22-26 August 2015	31 <sup>st</sup> Annual Conference ICPE	Boston MA, USA	International Society for Pharmacoepidemiology (ISPE) www.pharmacoepi.org
9-10 September 2015	Back to Basics in Pharmacovigilance	Fareham, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
14 September - 9 October 2015	The WHO Collaborating Centre Pharmacovigilance Fellowship	Accra, Ghana	WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance Tel: +233 302 268 746 / +233 289 014 000 www.who-pvafrica.org E-mail: training@who-pvafrica.org
16-18 September 2015	Patient Engagement in Benefit-Risk Assessment throughout Medical Products Life Cycle	Bethesda MD, USA	DIA www.diaglobal.org/en/Meetings-and-Training/
21-23 September 2015	Advanced Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
23-24 September 2015	Critical Appraisal of Medical and Scientific Papers	Fareham, UK	Drug Safety Research Unit (See above for contact details)
30 September - 1 October 2015	Pharmacovigilance Planning and Risk Management	Fareham, UK	Drug Safety Research Unit (See above for contact details)
30 September - 2 October 2015	Inter-Regional Pharmacovigilance Training 2015	Singapore	WHO-UMC-HSA Fax: +65 6478 9069 E-mail: choong_chih_tzer@hsa.gov.sg / leng_xue_zhen@hsa.gov.sg
13-14 October 2015	9 <sup>th</sup> Annual QPPV Forum	London, UK	DIA (See above for contact details)
14-15 October 2015	Assessment and Medical Evaluation of Individual Case Reports	Fareham, UK	Drug Safety Research Unit (See above for contact details)
21-22 October 2015	Risk Benefit Assessment in Pharmacovigilance	Fareham, UK	Drug Safety Research Unit (See above for contact details)
27-30 October 2015	ISoP 2015 Annual Meeting	Prague, Czech Republic	International Society of Pharmacovigilance www.isop2015prague.org E-mail: administration@isoponline.org
3-4 November 2015	Benefit/Risk Management	Paris, France	DIA Europe www.diahome.org/en-GB/Meetings-and-Training/
31 October - 2 November 2015	15 <sup>th</sup> Annual Conference of the Society of Pharmacovigilance, India	Kolkata, India	SOPi/Department of Clinical & Experimental Pharmacology, Calcutta School of Tropical Medicine, Kolkata www.sopi.in/ E-mail: orgsecy.sopicon2015@gmail.com
5-6 November 2015	Signal Management in Pharmacovigilance	Paris, France	DIA Europe (See above for contact details)
10-12 November 2015	Monitoring the Effectiveness of Risk Minimisation	Southampton, UK	Drug Safety Research Unit (See above for contact details)
14-16 November 2015	The ISPE 9 <sup>th</sup> Asian Conference on Pharmacoepidemiology	Bangkok, Thailand	ISPE www.pharmacoepi.org/
24 November 2015	4 <sup>th</sup> Nordic Pharmacovigilance Conference	Stockholm, Sweden	Läkemedelsakademien www.lakemedelsakademien.se/produkt/4th-nordic-pharmacovigilance-conference/?lang=en
25-27 November 2015	2 <sup>nd</sup> ASoP conference 'Pharmacovigilance In Africa : New Methods, New Opportunities, New Challenges'	Accra, Ghana	African Society of Pharmacovigilance (ASoP) www.asop2015.com E-mail: info@asop2015.com
18-29 January 2016	Asia Pacific pharmacovigilance training course	Mysore, India	JSS University, UMC E-mail: pvtraining@jssuni.edu.in
20-22 January 2016	Medical Aspects of Adverse Drug Reactions	Fareham, UK	Drug Safety Research Unit (See above for contact details)
25-27 January 2016	Pharmacovigilance and Risk Management Strategies	City to be confirmed	DIA www.diaglobal.org/en/Meetings-and-Training





– Building a global safety culture

The Uppsala Monitoring Centre (UMC) is a not-for-profit foundation and an independent centre of scientific excellence in the area of pharmacovigilance and patient safety. We provide essential research, reference, data resources and know-how for national pharmacovigilance centres, regulatory agencies, health professionals, researchers and the pharmaceutical industry round the world.

Many of our services and products have been developed as a result of our responsibility – as a World Health Organization Collaborating Centre – for managing the WHO pharmacovigilance network of over 120 countries and the WHO global individual case safety report database, VigiBase®. A core function is the screening and analysis of data with the aim of detecting potential issues of public health importance in relation to the use and safety of medicines. Other services include technical and scientific support to WHO and its member countries, and provision of tools, such as VigiLyze™ and VigiFlow®, for data entry, management, retrieval and analysis.

Our main commercially available products are the family of international WHO Drug Dictionaries, used by most major pharmaceutical companies and CROs.

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About UMC > UMC staff – on our website.

Internet: [www.who-umc.org](http://www.who-umc.org)

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Editors: Sten Olsson and Geoffrey Bowring

Uppsala Reports ISSN 1651-9779



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